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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,713	11/27/2000	Genichiro Soma	101149-00008	7273

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,713	SOMA ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/18/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16 and 18-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 6/18/2004 has been entered.

2. Applicants' amendment, received April 24, 2003 is acknowledged. The amendment has been entered. Claims 15 and 18 have been amended.

3. Currently claims 15-16 and 18-26 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Rejections Maintained

6. Rejection of claims 15-16 under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819) is maintained.

The rejection was as stated below:

Claims are drawn to a product prepared from gram negative bacteria, that has a

molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish. However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. (US Patent No. 5,494,819) teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of 5,000 ± 1000 and 6,500 ± 2,500 as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see abstract and claim 1).

Applicants argue that Soma et al. disclose a lipopolysaccharide (LPS) composition, which is partially purified, also containing high molecular weight LPS, and used as a feed or feed additive. For example, fig 1 of the specification of Soma et al. illustrates that LPS disclosed also contains HMW-LPS. Applicants further argue in contrast to Soma et al, in the present invention the feed- stuff additive LMW-LPS is further purified by removing HMW-LPS.

Therefore, the LMW-LPS of claim 15, as amended, is different from the LPS material in Soma et al, because the LPS material of Soma et al. is further purified in the present invention to no longer contain HMW-LPS.

Applicants' arguments have been fully considered but they are not persuasive.

It is the examiner's position that the rejected claims are drawn to a product and the same product is taught by Soma et al. However, how the product is produced does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. disclose a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysacchride and capable of activating immunity (see abstract). Soma et al. teach that the crude LPS fractions are then purified conventionally (see columns 3, lines 37-43). Soma et al. teach 96% or purity for the product (see columns 3, lines 44-55). The product of Soma et al. can be considered 97%, 98%, 99% or even 100% pure.

Applicants claim that their product is free of high molecular weight LPS. Amended claim 15 step A recites, " wherein the high molecular LPS is removed". It is not clear from the applicants' recitation what is the degree of the purity reciting said language. The term "removed" can be interpreted any where equal or less than 100% removal of the high molecular LPS.

A contradiction of term now appears due to the amendment of claim 15 between step A and step C. Amended claim 15 step A recites " wherein the high molecular LPS **is removed**" wherein step C recites that the product is **substantially free** of high molecular weight LPS. It is not clear from the applicants' recitations what is the degree of purity of the claimed product (see

112 2nd paragraph rejection below). Is the recitation in step A " wherein the high molecular LPS is removed" means that the product is 100% free of HMW LPS? On the other hand step C implies that the product is somewhat free of HMW LPS.

7. Rejection of claims 18-26 under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (US Patent No. 5,641,761) in view of Soma et al. (US Patent No.5, 494,819) is maintained.

The rejection was as stated below:

Claims are drawn to a method of activating immunity or preventing infection in crustaceans or fish comprising administering an effective amount of low molecular weight lipopolysaccharide to crustaceans or fish.

Takahashi et al. teach a method of activating immunity or preventing infection in crustaceans comprising administering or feeding a polysaccharide to crustaceans (see claims). Takahashi et al teach a method of enhancing the immune system of crustaceans (Kuruma prawns, see examples 1-7). Takahashi et al teach a method of treating crustaceans' infections such as vibrio infections, mycotic infections, and viral infections. Takahashi et al. do not teach low molecular weight lipopolysaccharide. However Soma et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to modify the method taught by Takahashi et al. by using the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. with the low molecular weight lipopolysaccharide of Soma et al. which has excellent immuno-stimulating activity and may be provided at low cost and a large amount (see Soma et al., column 2, line 50-55). Limitations such as concentration of the feed are being viewed as limitations of optimizing experimental parameters.

Applicants submit that Takahashi et al. teach the use of a particular polysaccharide in feed for crustaceans and fish to activate immunity, prevent infection and treat infection in crustaceans. Takahashi et al. use a polysaccharide derived from mushrooms. They also noted that it was suggested in the literature that polysaccharide from bacteria exhibits similar biological activities. Applicants further state that Takahashi et al. suggests that the effect of a polysaccharide in activating immunity in one animal does not confirm the same effect in crustaceans. Applicants further argue that Soma et al. merely teaches that LMW -LPS in feed for veterinary use activates immunity in animals. However, Soma et al. do not teach or suggest the use of LMW – LPS in feed for crustaceans and fish activates immunity.

Applicants' arguments have been fully considered but they are not persuasive.
It is the examiner's position that as the applicants submit Takahashi et al. teach the use of a polysaccharide in feed for crustaceans and fish to activate immunity, prevent infection and treat infection in crustaceans. Contrary to applicants arguments that Takahashi et al. suggest that the effect of a polysaccharide in activating immunity in one animal does not confirm the

same effect in crustaceans, Takahashi et al. column 1, lines 52-55 recite that their polysaccharide shows effects for preventing infectious diseases and enhancing the immune system of fish and crustacean. Soma et al. as discussed supra teach a low molecular weight lipopolysacchride capable of activating immunity.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Takahashi et al. teach that polysaccharides isolated from various organisms enhance immune system of various living organisms including fish and crustacean (see column 1). Soma et al. teach low molecular weight lipopolysaccharide, which has excellent immuno-stimulating activity and may be provided at low cost and a large amount (see Soma et al., column 2, line 50-55). Therefore, one having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. with the low molecular weight lipopolysaccharide of Soma et al. Limitations such as concentration of the feed are being viewed as limitations of optimizing experimental parameters.

New Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 18 step A recite " wherein the high molecular LPS is **removed**", in direct contradiction to step A, step C recites that the product is **substantially free** of high molecular weight LPS. It is not clear from the applicants' recitations what is the degree of purity of the claimed product. Does the product contain any HMW –LPS or it is 100% free of HMW-LPS?

Claims 16 and 19-26 are indefinite as being dependent from indefinite claims 15 and 18.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from7: 30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

08/20/2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER